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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,194	03/24/2004	R. Elaine Fulton	NEL-0020	3760

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EXAMINER	
SALVOZA, M FRANCO G	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/807,194	FULTON ET AL.	
	Examiner	Art Unit	
	M. Franco Salvoza	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *06/17/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-5 are pending and under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 further recites the method of claim 2, wherein said biotinylated scFv Ab displays high streptavidin-binding activity. It is not clear what is intended by "high" activity. "High" activity is a relative term subject to individual interpretation. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to the method of detecting Venezuelan equine encephalitis virus wherein the biotinylated scFv antibody displays high streptavidin-binding activity and wherein a concentration ratio of biotinylated antibody to fluoresceinated polyclonal antibody of 250:500 (ng/spot) provides the highest signal to noise ratio with fixed concentration of VEE. The claims do not require that the antibodies possess any particular distinguishing feature, biologic activity, or conserved structure. Therefore, the claims are drawn to a genus of antibodies that are defined only by binding affinities and a proportion indicating highest signal to noise ratio.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

In this case, the only factors present in the claims are indications of binding affinity to streptavidin and a desired antibody concentration for the highest signal to noise ratio based on a fixed concentration of virus. There is not even identification of any particular portion of the structure that must be conserved, or which structural components correlate to the cited functions. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al. (2002) in view of Lee et al. (1993)

Claim 1 recites a method for detecting Venezuelan equine encephalitis virus ("VEE") using a genetically biotinylated single chain fragment variable antibody ("scFv Ab"), comprising: (a) reacting the genetically biotinylated scFv Ab with a sample containing VEE for observing antigen-binding activity, and (b) analyzing the reactant by a system consisting of an immunofiltration enzyme assay (IFA) with a light addressable potentiometric sensor/ ("LAPS")

Claim 2 further recites the method of claim 1, wherein said genetically biotinylated scFv Ab is a genetically streptavidin-binding peptide tagged recombinant biotinylated scFv Ab. Claim 3 further recites the method of claim 2, wherein said biotinylated scFv Ab displays high streptavidin-binding activity.

Claim 4 further recites the method of claim 2, wherein said IFA assay comprises the steps of: (a) preparing an immunocomplex sandwich, said sandwich consisting of VEE, biotinylated antibody, fluoresceinated polyclonal antibody and streptavidin, (b) capturing said sandwich by filtration on biotinylated membrane; and (c) detecting said captured sandwich by anti-fluorescein urease conjugate.

Finally, claim 5 further recites the method of claim 4, wherein a concentration ratio of biotinylated antibody to fluoresceinated polyclonal antibody of 250:500 (ng/spot) provides the highest signal to noise ratio with fixed concentration of VEE.

Hu et al. teaches a genetically biotinylated, streptavidin-binding peptide tagged, single chain fragment variable antibody against Venezuelan Equine Encephalitis (p. 419). The fusion protein exhibited strong binding activity to VEE (p. 419).

Hu et al. does not teach a method of analyzing the sample for antigen binding using a system consisting of an immunofiltration assay ("IFA") with a light addressable potentiometric sensor ("LAPS").

Lee et al. teaches a sandwich immunofiltration assay which comprises the steps of preparing an immunocomplex sandwich consisting of an antigen, a biotinylated antibody, a fluoresceinated polyclonal antibody, and streptavidin (p. 123, p. 125 (Fig. 1)). The assay captures the sandwich by filtration on a biotinylated membrane and detects by antifluorescein urease conjugate (p. 123, p. 125 (Fig. 1)). Further, the immunoassay apparatus employs a light addressable potentiometric sensor (p. 124).

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the genetically biotinylated antibody of Hu et al. and the immunofiltration assay of Lee et al. because Lee et al. teaches that the immunofiltration assay can detect complexes formed by incubation of antibodies with antigens in an efficient, rapid process, and further, that the assay is suitable for a variety of viral, bacterial and protein antigens (p. 123).

One of ordinary skill in the art at time the invention was made would have had a reasonable expectation of success for using the genetically biotinylated antibody of Hu et al. with the immunofiltration assay of Lee et al. because Hu et. al. and Lee et al. both teach using immunoassays that detect viral antigens complexed with antibodies.

Therefore, the invention as a whole would have been prima facie obvious to one of

ordinary skill in the art at the time the invention was made.

The applied reference has common inventors with the instant application. This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claim 3 recites the functional limitation that the antibody displays high streptavidin-binding activity. Claim 5 recites that a concentration ratio of biotinylated antibody to fluoresceinated polyclonal antibody of 250:500 (ng/spot) provides the highest signal to noise ratio with a fixed concentration of VEE. The antibody suggested by Hu et al. meets the structural limitation of the claims, and is therefore considered to meet the functional limitations of claims 3 and 5 unless special structural distinctions are indicated otherwise. See MPEP 2112 V.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Franco Salvoza
Patent Examiner

3/20/06

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